Listing of Claims

This listing of claims will replace prior versions and listings of claims in the application:

Claims 1-40 (Cancelled)

41. (New) A method for determining a predisposition for or presence of prostate cancer in a patient comprising:

(a) performing an RNA amplification assay on a urine sample of said patient comprising at least one prostate cell, or nucleic acid extract thereof, using a first primer pair specific to a prostate cancer specific PCA3 mRNA sequence selected from the group consisting of:

i) a polynucleotide comprising SEQ ID NO: 9, 10 or 13;

ii) a polynucleotide sequence that hybridizes under high stringency conditions to the polynucleotide sequence in i), wherein said high stringency conditions comprise a hybridization at 65°C in 6X SSC or 5X SSPE, 5X Denhardt's solution, 0.5% SDS and 100 μg/ml denatured carrier DNA and a washing at 65°C in 0.2X SSC/0.1% SDS; and

iii) a polynucleotide sequence fully complementary to i) or ii);

(b) performing a second RNA amplification assay on said urine sample comprising at least one prostate cell, or nucleic acid extract thereof, using a second primer pair specific to a second prostate-specific mRNA sequence;

(c) detecting said PCA3 mRNA sequence and said second prostate-specific mRNA sequence;

(d) correlating a detection of said PCA3 mRNA sequence or a level thereof, as compared to a PCA3 mRNA or a level thereof associated with a normal or non-malignant prostate state, with a risk of developing prostate cancer or a presence of prostate cancer in said patient; and

(e) correlating an absence of detection of said PCA3 mRNA sequence or lower level thereof, as compared to a PCA3 mRNA sequence or a level thereof associated with a normal or non-malignant prostate state, with an absence of

prostate cancer or a lower risk of developing same, when said second prostate-specific mRNA is detected.

42. (New) The method of claim 41, wherein said RNA amplification assay is carried out in real-time.

43. (New) The method of claim 41, wherein said detection is performed by fluorescence, chemiluminescence or colorimetry detection.

44. (New) The method of claim 41, wherein the detection of said second prostate-specific mRNA validates the presence of at least one prostate cell in said urine sample.

45. (New) The method of claim 41, wherein said second prostate-specific mRNA is selected from the group consisting of: PSA, human kallikrein 2, PSMA, transglutaminase 4, acid phosphatase, and PCGEM1 mRNA.

46. (New) The method of claim 45, wherein said second prostate-specific mRNA is PSA mRNA.

47. (New) The method of claim 46, wherein said PSA mRNA hybridizes to human kallikrein 2.

48. (New) The method of claim 41, wherein said RNA amplification method is selected from the group consisting of:

(a) nucleic acid sequence-based amplification (NASBA);

(b) polymerase chain reaction (PCR);

(c) transcription-mediated amplification assay (TMA); and

(d) ligase chain reaction.

49. (New) The method of claim 42, wherein said RNA amplification method is selected from the group consisting of:

(a) nucleic acid sequence-based amplification (NASBA);

(b) polymerase chain reaction (PCR);

(c) transcription-mediated amplification assay (TMA); and

(d) ligase chain reaction.

50. (New) The method of claim 41, wherein said amplification of PCA3 and said second prostate-specific mRNA is performed simultaneously.

51. (New) The method of claim 41, wherein said amplification of PCA3 is carried out using a primer pair comprised of the polynucleotide sequences set forth in SEQ ID NOs: 3 and 4.

52. (New) The method of claim 41, wherein said detection of PCA3 is carried out using a molecular beacon.

53. (New) The method of claim 52, wherein said molecular beacon comprises the sequence set forth in SEQ ID NO: 6.

54. (New) The method of claim 46, wherein said amplification of PSA is carried out using a primer pair comprised of the polynucleotide sequences set forth in SEQ ID NOs: 1 and 2.

55. (New) The method of claim 46, wherein said detection of PSA is carried out using a PSA molecular beacon.

56. (New) The method of claim 55, wherein said PSAmolecular beacon comprises the sequence set forth in SEQ ID NO: 5.

57. (New) The method of claim 50, wherein said simultaneous amplification is carried out in one container.

58. (New) The method of claim 46, wherein said detection of PSA is carried out using a chemiluminescent label in a homogenous detection method.

59. (New) The method of claim 43, wherein said detection of PCA3 is carried out using acridinium ester compounds.

60. (New) The method of claim 58, wherein said chemiluminescent label is an acridinium ester.

61. (New) The method of claim 41, wherein said mRNA is extracted from said at least one prostate cell.

62. (New) The method of claim 61, wherein said RNA is extracted using
(a) a silica based purification method; or
(b) a target capture method.

63. (New) The method of claim 41, wherein said urine sample is a voided urine sample from a patient having an increased number of prostate cells therein.

64. (New) The method of claim 62, wherein said RNA is extracted using a silica-based method.

65. (New) The method of claim 63, wherein said urine sample is collected following a digital rectal exam.

66. (New) The method of claim 63, wherein said urine sample contains semen.

67. (New) A method for determining a predisposition for or presence of prostate cancer in a patient comprising:
(a) performing an RNA amplification assay on a urine sample of said patient comprising at least one prostate cell, or nucleic acid extract thereof, using a first primer pair specific to a prostate cancer specific PCA3 mRNA sequence selected from the group consisting of:

i) a polynucleotide comprising SEQ ID NO: 9, 10 or 13;

ii) a polynucleotide sequence that hybridizes under high stringency conditions to the polynucleotide sequence in i), wherein said high stringency conditions comprise a hybridization at 65°C in 6X SSC or 5X SSPE, 5X Denhardt's solution, 0.5% SDS and 100 µg/ml denatured carrier DNA and a washing at 65°C in 0.2X SSC/0.1% SDS; and

iii) a polynucleotide sequence fully complementary to i) or ii);

(b) performing a second RNA amplification assay on said urine sample comprising at least one prostate cell, or nucleic acid extract thereof, using a second primer pair specific to a second prostate-specific mRNA sequence;

(c) detecting said PCA3 mRNA sequence and said second prostate-specific mRNA sequence;

(d) correlating a higher detection of said PCA3 mRNA, as compared to a predetermined cut off value associated with a normal or non-malignant prostate state, with a risk of developing prostate cancer or a presence of prostate cancer in said patient; and

(e) correlating an absence of detection or lower detection of said PCA3 mRNA, as compared to said predetermined cut off value associated with a normal or non-malignant prostate state, with an absence of prostate cancer or a lower risk of developing same, when said second prostate-specific mRNA is detected.

68. (New) The method of claim 41, wherein said detection of PCA3 is carried out using chemiluminescent labels in a homogenous detection method.

69. The method of claim 68, wherein said detection of PCA3 is carried out using an acridinium ester compounds.